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	BEFORE THE				
	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS				
	STATE OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
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3	In the Matter of the Accusation Against:	Case No. 7223			
	ADVANTAGE HEALTH CARE HIV &	ACCUSATION			
5	COMPOUNDING INC., DBA GARDEN GROVE COMMUNITY				
5	PHARMACY, VIMAL BHANVADIA AND SHEKHA DASHRATH PATEL,				
7	OFFICERS AND SHAREHOLDERS 12665 Garden Grove Blvd., Ste. 108				
3	Garden Grove, CA 92843				
)	Pharmacy Permit No. PHY 51109,				
	and				
)	SHEKHA DASHRATH PATEL 12665 Garden Grove Blvd., Ste. 108				
	Garden Grove, CA 92843				
ı	Pharmacist License No. RPH 60337				
ļ	Respondents. In the Matter of the Statement of Issues	Case No. 7210			
,	Against:	STATEMENT OF ISSUES			
	AHCS SPECIALTY CARE, LLC				
,	Applicant for Pharmacy Permit				

ACCUSATION AND STATEMENT OF ISSUES

In the Matter of the Statement of Issues	Case No. 7211		
Against:	STATEMENT OF ISSUES		
ADVANTAGE HEALTH CARE SERVICES-MISSION INC., DBA MISSION PLAZA PHARMACY 3			
Applicant for Pharmacy Permit			
Respo	ondent.		
	<u>PARTIES</u>		
1. Anne Sodergren (Complainar	nt) brings the Accusation and Statement of Issues solely		
in her official capacity as the Executive Officer of the Board of Pharmacy, Department of			
Consumer Affairs.			
2. On or about November 19, 20	012, the Board of Pharmacy issued Pharmacy Permit		
Number PHY 51109 to Advantage Health Care HIV & Compounding Inc., dba Garden Grove			
Community Pharmacy and identified Vimal Bhanvadia as the president and twenty percent			
shareholder of Advantage Health Care HIV & Compounding, Inc. and Shekha Dashrath Patel as			
the Vice-President, Pharmacist-in-Charge and twenty percent shareholder of Advantage Health			
Care HIV & Compounding, Inc. (Garden Grove Community Pharmacy). The Pharmacy Permit			
was in full force and effect at all times relevant to the charges brought herein and will expire on			
November 1, 2022, unless renewed.			
3. On or about October 10, 2007	7, the Board of Pharmacy issued Pharmacist License		
Number RPH 60337 to Shekha Dashrath Patel. The Pharmacist License was in full force and			
effect at all times relevant to the charges brought herein and will expire on September 30, 2023,			
unless renewed.			
4. On or about January 22, 2021	, the Board received an application for a pharmacy		
permit from Advantage Health Care Services-Mission, Inc., dba Mission Plaza Pharmacy 3 with			
Vimal Bhanvadia identified as a fifteen percent shareholder and officer and Shekha Dashrath			
Patel identified as a fourteen percent shareholder and director. On or about October 8 and 13,			
2020. Shekha Dashrath Patel and Vimal Bhanyadia certified under penalty of periury to the			

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STATUTORY PROVISIONS 1 11. Code section 4022 states: 2 3 "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following: 4 (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing 5 without prescription," "Rx only," or words of similar import. 6 (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ""Rx only," or words of similar import, the 7 blank to be filled in with the designation of the practitioner licensed to use or order use of the device. 8 (c) Any other drug or device that by federal or state law can be lawfully 9 dispensed only on prescription or furnished pursuant to Section 4006. 10 12. Code section 4043 states: 11 'Wholesaler' means and includes a person who acts as a wholesale merchant, 12 broker, jobber customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler 13 may not store, warehouse, or authorize the storage or warehousing of drugs with any 14 person or at any location not licensed by the board. 15 13. Code section 4059.5, subdivision (a) states: 16 Except as otherwise provided in this chapter, dangerous drugs or dangerous 17 devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a 18 licensee is permitted to operate through a designated representative, or in the case of a reverse distributer, a designated representative-reverse distributor, that individual 19 shall sign for and receive the delivery. 14. Code section 4113, subdivision (c) states: 20 21 The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. 22 15. Code section 4160, subdivision (a) states: 23 24 A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the 25 board.

Code section 4169, subdivisions (a)(1) and (a)(4) state:

(a) A person or entity shall not do any of the following:

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16.

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or

28. <u>Triumeq</u> is a high priced drug used to treat HIV and is a dangerous drug as defined by Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

- 29. Garden Grove Community Pharmacy is an open door, retail community pharmacy located in Garden Grove, California. It dispenses high value, HIV medications to patients throughout California.
- 30. Shekha Dashrath Patel is the Pharmacist-in-Charge and a partial owner and officer of the corporation that owns Garden Grove Community Pharmacy. Vimal Bhanvadia manages finances and creates accounts with wholesalers for the pharmacy and is a partial owner and officer of the corporation that owns Garden Grove Community Pharmacy.
- 31. Premier Rx Wholesale is a wholesaler located at 4637 Interstate Drive, Cincinnati, Ohio 45246, and holds an out of state distributor license (OSD 7553) with the Board. In 2019-2020, its identity was stolen and its license used to sell HIV drugs obtained from unknown and highly suspicious sources on the secondary market.
- 32. Garden Grove Community Pharmacy claimed to have "extensive protocols in place to verify [its] secondary wholesalers, including verification on the BOP website, which is conducted quarterly to ensure that the drug products we purchase are unadulterated."
- 33. Yet, on or about March 8, 2019, Garden Grove Community Pharmacy did not require Premier Rx Wholesale LLC to submit an application, nor did Garden Grove Community Pharmacy verify all of the information listed for Premier Rx Wholesale LLC on the Board's website and the out of state distributor license, including confirming the physical address, telephone number and email address for Premier Rx Wholesale LLC and resolving any discrepancies between the information provided by Premier Rx Wholesale LLC and the information on the Board's website and Premier Rx Wholesale LLC's license.
- 34. From March 22, 2019 to May 26, 2020, Garden Grove Community Pharmacy purchased 9,170 medication packages of the HIV drugs, Genvoya, Biktarvy, Truvada, Triumeq and others from individuals or an organization using the name and license of Premier Rx

Wholesale LLC. These purchases comprised almost half of Garden Grove Community Pharmacy's HIV drug inventory.

- 35. Garden Grove Community Pharmacy paid \$19,531,015.26 to the individuals or an organization pretending to be Premier Rx Wholesale LLC. Garden Grove Community Pharmacy paid for these purchases via checks signed by Vimal Bhanvadia or Shekha Patel. Garden Grove Community Pharmacy also paid Premier Rx Wholesale LLC for drugs never shipped or received by Garden Grove Community Pharmacy. Almost all of these HIV drugs or 9138 medication packages were dispensed to patients.
- 36. Garden Grove Community Pharmacy received invoices and pedigrees¹ for these drugs from individuals or an organization posing as Premier Rx Wholesale LLC. The invoices and pedigrees listed a different physical and email address for Premier Rx Wholesale LLC, than was listed on the Board's website and the out of state distributor license. Additionally, the invoices listed a telephone number for another entity, Wealth Transfer Services Credit Repair in Florida, as the telephone number for Premier Rx Wholesale LLC.
- 37. On December 9, 2019, Garden Grove Community Pharmacy asked Premier Rx Wholesale LLC to confirm its physical address because the address for Premier Rx Wholesale LLC listed on the Board's website was different than the address listed on the invoices. The individuals or organization posing as Premier Rx Wholesale LLC did not provide an explanation for the discrepancy and instead, merely re-sent a copy of Premier Rx Wholesale LLC's license.
- 38. On May 27, 2020, the manufacturer of a HIV medication drug, Biktarvy informed Garden Grove Community Pharmacy that it may have purchased counterfeit or diverted drugs from an unauthorized distributor, Premier Rx Wholesale LLC and requested that Garden Grove Community Pharmacy quarantine bottles of Biktarvy purchased from Premier Rx Wholesale LLC.
- 39. In June 2020, Garden Grove Community Pharmacy continued to pay the individuals or organization posing as Premier Rx Wholesale LLC's invoices and expressed its desire to

¹ A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties.

"reengage" with Premier Rx Wholesale LLC to purchase more drugs. After receiving notice that the Board was investigating Garden Grove Community Pharmacy for its dispensing of a bottle of Biktary with just rocks in it, Garden Grove Community Pharmacy finally informed the individuals or organization posing as Premier Rx Wholesale LLC that it would no longer purchase drugs from Premier Rx Wholesale LLC, noting "there are concerns around product integrity with Premier's supply chain. As previously discussed, patient safety is our number one priority and therefore we will be suspending purchases from Premier until further notice. Our primary responsibility is to mitigate any risk to our patients and ensure compliance with BOP regulations."

- 40. On July 15, 2020, the Board issued a notice of non-compliance with Pharmacy Law to Garden Grove Community Pharmacy for purchasing drugs from an unlicensed wholesaler, Premier Rx Wholesale LLC.
- 41. On July 20, 2020, Garden Grove augmented it procedures for purchasing drugs from secondary wholesalers, to include a requirement to quarantine drugs purchased from wholesalers whose address on invoices and pedigrees did not match the address on their license and the Board's website.
- 42. On September 3, 2020, the manufacturer of Biktarvy notified Garden Grove
 Community Pharmacy that its investigation into the potentially counterfeit or diverted drugs sold
 by Premier Rx Wholesale LLC was on-going. The manufacturer advised Garden Grove
 Community Pharmacy that drugs sold by Premier Rx Wholesale LLC were "sourced from non[manufacturer] authorized distributors which increases the risks that these bottles are suspect or
 illegitimate. If you chose to dispense the [potentially counterfeit or diverted drugs], be aware of
 the serious risks, both to patients' health and to Garden Grove's ability to operate as a pharmacy,
 associated with selling counterfeit medications."
- 43. Nonetheless, Garden Grove Community Pharmacy continued to dispense drugs purchased from the individuals or an organization posing as Premier Rx Wholesale LLC to patients until December 30, 2020.

Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Business and Professions Code section 4169, subdivision (a)(1), because they purchased and/or warehoused drugs from unlicensed individuals or an organization, as

(Held or Offered for Sale Adulterated Drugs Against Respondents)

Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111295 and Code section 4169, subdivision (a)(2), in that they held or offered for sale dangerous drugs that were adulterated within the meaning of Health and Safety Code section 111255, as described above, in paragraphs

Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111295 and Code section 4169, subdivisions (a)(2), in that they sold or delivered dangerous drugs that were adulterated within the meaning of Health and Safety Code section 111255 and sold them after the beyond use date, as

(Inappropriate Exercise of Education, Training or Experience

Respondent Shekha Patel is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Business and Professions Code section 4306.5, subdivision (a), because she inappropriately exercised her education, training, or experience as a pharmacist when dispensing dangerous drugs, as described above, in paragraphs 29 through 43.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct against All Respondents)

48. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct because they engaged in the activities described above, in paragraphs 29 through 43.

DISCIPLINE CONSIDERATIONS

49. To determine the degree of discipline, if any, to be imposed on Respondents Advantage Health Care HIV & Compounding, Inc., dba Garden Grove Community Pharmacy and Shekha Dashrath Patel, Complainant alleges that on or about May 11, 2021, the Board issued Citation and Fine No. CI 2019 88503 to Advantage Health Care HIV & Compounding, Inc., dba Garden Grove Community Pharmacy for violating Business and Professions Code section 4169, subdivision (a), purchasing thirty-six dangerous drugs from two unlicensed wholesalers and Health & Safety Code sections 111250 and 111295 for dispensing an adulterated drug. That Citation is now final. On May 11, 2021, the Board issued Citation No. CI 2020 91188 to Shekha Dashrath Patel for violating Business & Professions Code section 4169, subdivision (a), purchasing thirty-six dangerous drugs from two unlicensed wholesaler. That Citation is now final.

OTHER MATTERS

- 50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 51109 issued to Advantage Health Care HIV & Compounding, Inc., dba Garden Grove Community Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51109 is placed on probation or until the Pharmacy Permit is reinstated if it is revoked.
- 51. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 51109 issued to Advantage Health Care HIV & Compounding, Inc., dba Garden Grove Community Pharmacy while Vimal Bhanvadia has been a manager, owner, officer or director and had knowledge of or knowingly participated in any conduct for which the licensee was

STATEMENT OF ISSUES AGAINST

AHCS SPECIALTY CARE, LLC

CAUSE FOR DENIAL

(Various)

55. Respondent AHCS Specialty Care, LLC's application is subject to denial under Code sections 4300, subdivision (c), 4301, subdivisions (j) and (o) and 4302 for violating the statutes and regulations referenced in the Accusation, which are incorporated herein by reference.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacy License Number PHY 51109 issued to Advantage
 Health Care HIV & Compounding, Inc., dba Garden Grove Community Pharmacy;
- 2. Revoking or suspending Pharmacist License Number RPH 60337 issued to Shekha Dashrath Patel;
- 3. Prohibiting Advantage Health Care HIV & Compounding, Inc., dba Garden Grove Community Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51109 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;
- 4. Prohibiting Shekha Dashrath Patel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51109 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;
- 5. Prohibiting Vimal Bhanvadia from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51109 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;
- 6. Prohibiting Shekha Dashrath Patel from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License

1	Number RPH 60337 is placed on probation or until the Pharmacist License is reinstated, if it is				
2	revoked;	red;			
3	7.	Ordering Advantage Health Care HIV & Compounding, Inc., dba Garden Grove			
4	Communit	Community Pharmacy and Shekha Dashrath Patel to pay the Board of Pharmacy the reasonable			
5	costs of the investigation and enforcement of this case, pursuant to Business and Professions				
6	Code section 125.3;				
7	8.	Denying the Application of Advantage Health Care Services-Mission, Inc., dba			
8	Mission Plaza Pharmacy 3 for a pharmacy permit;				
9	9.	Denying the Application of AHCS Specialty Care, LLC for a pharmacy permit; and,			
10	10.	Taking such other and	d further action as deemed necessary and proper.		
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12		2/24/2022	Signature on File		
13	DATED:	3/24/2022	ANNE SODERGREN		
14			Executive Officer Board of Pharmacy		
15			Department of Consumer Affairs State of California		
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